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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.	Applicant(s)	Applicant(s)		
10/570,010	BAMDAD, CYNTHIA C.	BAMDAD, CYNTHIA C.		
Examiner	Art Unit			
LYNN BRISTOL	1643			

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS.

- WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
- after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
- earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 June 2010.
- 2a) ☐ This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,13,14,17,27,57-62 and 196-199 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 57-62 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 13, 14, 17 and 196-199 is/are rejected.
- Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 - 1. Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 - * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Fatent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO/SB/08)
 - Paper No(s)/Mail Date

- 4) Interview Summary (PTO-413)
- Paper No(s)/Mail Date.___ 5) Notice of Informal Patent Application
- 6) Other:

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DETAILED ACTION

1. Claims 1, 13, 14, 17, 27, 57-62 and 196-199 are all the pending claims for this application.

- Claim 5 was cancelled, Claim 1 was amended, and new Claims 196-199 were added in the Response of 6/15/10.
- Claims 27 and 57-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).
- 4. Claims 1, 13, 14, 17 and 196-199 are all the pending claims under examination.
- Applicants amendments to the claims have necessitated new grounds for objection and rejection. The finality of the Office Action is withdrawn in view of the new grounds of rejection for Claims 17 and 199.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, second paragraph.

6. The rejection of Claims 1, 5, 13, 14 and 17 for reciting the broad recitation "An isolated monovalent antibody or antigen-binding fragment thereof that specifically binds to MUC1 Growth Factor Receptor (MGFR)", and the narrower statement of the range/ "the antibody or antigen-binding fragment thereof specifically binds to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR)" is withdrawn.

Applicants have amended the claims in the Response of 6/15/10 to recite the narrower limitation that the binding site falls within the sequence of SEQ ID NO: 36. Application/Control Number: 10/570,010 Page 3

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7. The rejection of Claim 5 for the recitation "An isolated antibody or antigen binding fragment" which is considered to be a broadening limitation for the species of antibody than what is claimed in Claim 1, namely, a monovalent antibody is moot in view of the

cancelled claim.

 The rejection of Claims 5, 13, 14 and 17 in lacking antecedent basis for the limitation "antibody or antigen binding fragment thereof" is moot for cancelled Claim 5 and withdrawn for claims 13, 14 and 17.

Claim Rejections - 35 USC § 112, first paragraph Written Description

9. The rejection of Claims 1, 5, 13, 14 and 17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims are drawn to the genus of monovalent antibodies having the combined properties of a) binding to MUC1 Growth Factor Receptor (MGFR)", b) binding to Primary Sequence of the MUC 1 Growth Factor Receptor (PSMGFR), and c) inhibiting proliferation of MUC1 expressing cells is withdrawn.

Applicants have amended the claims in the Response of 6/15/10 to delete the conflicting limitations for a) and c) in Claim 1.

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Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The rejection of Claims 1, 13, and 14 (and new Claims 196, 197 and 198) under
 U.S.C. 102(e) as being anticipated by Wreschner et al. (US 20050019324; published
 1/27/05; filed 3/26/02; cited in the PTO 892 form of 1/31/08) is maintained.

Claim 196 is drawn to bivalent antibodies, and Claims 197 and 198 are joined under this rejection because they are drawn to the same subject matter of Claims 13 and 14.

The rejection was maintained in the Office Action of 10/31/08 as follows:

"Applicants' allegations on p, 9 of the Response of 7/31/08 have been considered but cit en to found persuasive. Applicants allege "Wreschner discoses a monoclonal antibody (BoS7010) against MUC1 that inhibits cell growth. However, the disclosed antibody appears to be a bi-valent antibody. Since Wreschner is silent as to the anti-cell proliferation effects of the monovalent antibody over bivalent antibody the presently claimed monovalent antibody is distinguished over the bivalent antibody described in Wreschner."

Personse to Arouments

Integration of Significants of Significants and Significant Signif

Wreschner's disclosure for making monoclonal antibodies is explicit. Wreschner's disclosure for making monovalent antibodies is explicit. Applicants' argument that Wreschner does not appreciate the difference(s) between

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monovalent and bivalent antibodies is irrelevant and gratuitous because none of the instant claims are drawn to a bivalent antibody. The rejection is maintained."

The rejection was maintained in the Office Action of 6/15/10 as follows:

"Applicants' allegations on pp. 6-7 of the Response of 11/10/09 have been considered but are not found persuasive. Applicants allege Wreschner '324 discloses that its antibody was preferably made against the sequence located in the 15 amino acid sequence that resides at the N-terminal portion of the 59 amino acid segment. This 15 amino acid sequence includes SVWOLTLAFREGTI. However, only the final "GTI" overlaps with the PSMGFR sequence of the claimed invention. Accordingly, it is believed that the Wreschner '324 antibody lies outside the scope of the antibody of the claimed invention.

Response to Arguments

The examiner respectfully submits that Applicants have not established by a preponderance of the evidence that the epitope for the monovalent antibody of Wreschner would not comprise or be overlapping with the final "GTI" residues of the PSMGFR sequence. Also Wreschner teaches examples of monoclonal antibodies binding within this region and having the property of growth inhibition of MCF7 breast cancer cells.

The claimed antibody appears to be the same as the prior art antibodies, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the faculate vidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989)."

Applicants allegations on pp. 5-6 of the Response of 6/15/10 have been considered and are not found persuasive. Applicants allege Wreschner '324 discloses that its antibody was preferably made against the 15 amino acid sequence SVVVQLTLAFREGTI. Since only the final "GTI" overlaps with the PSMGFR sequence of the claimed invention, the Wreschner '324 antibody lies outside the scope.

Response to Arguments

a) Applicants have not disclosed the epitope for the inventive antibody.

Applicants have disclosed the sequence of SEQ ID NO:36 as comprising the binding site for the inventive antibody. Applicants make the bald face assertion that because 12 residues of Wreschner '324 lies outside the claimed range and 3 residues of Wreschner '324 fall within the range, that Wreschner '324 is not effective art. No where have Applicants shown which amino acid residues of the sequence are critical for antibody binding. No where have Applicants shown that the "GIT" region of the sequence is

excluded from antibody binding. Applicants attorney arguments are unsubstantiated by any evidence. If Applicants wish to maintain this same position, then they are requested to provide data showing that the "GIT" residues are not critical for binding, and are otherwise excluded from the claim scope for the antibody.

MPEP 2144.05 ("Optimization of Ranges") states in part:

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40 °C and 80 °C and an acid concentration between 25% and 70% was held to be prima facile obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100 °C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or moler proportions.)."

b) Wreschner '324 discloses at [0049] that antibody fragments can be bispecific single chain Fv dimers (PCT/US92/09965) and (ix) "diabodies", multivalent or multispecific fragments constructed by gene fusion. The meaning of the embodiments is considered to represent a bivalent antibody of the instant claims.

The rejection is maintained.

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11. The rejection of Claims 1, 13, 14 and 17 (and new Claims 196-199) under 35 U.S.C. 102(e) as being anticipated by Bamdad et al. (US 20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07) is maintained.

Claim 196 is drawn to bivalent antibodies, and Claims 197 and 198 are joined under this rejection because they are drawn to the same subject matter of Claims 13 and 14. Claim 199 is joined because it is drawn to kits.

The rejection was maintained in the Office Action of 10/31/08 as follows:

"Applicants' allegations on p, 8 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "The present application claims the benefit of priority to PCT/US2005/032821 (See the Declaration), which in turn claims priority to U.S. Application No. 09/996,099, which is the application number for the cited Bamdad '199 patent application publication. Therefore, Bamdad '199 is not citable against the present application."

Response to Arguments

The current filed Oath/ Declaration (2/27/06) does not list any of the above alleged priority information; the application transmittal letter of 227/06 does not list any of the above alleged priority information; the cross-reference to related applications in the original filed specification (2/27/06) does not list any of the above alleged priority information; and the filing receipt of 172/10/ does not list any of the above alleged priority information. Still further, the sequence listing does not list any of the above alleged priority information. No where in the file history is there documentation for the alleged priority dain. The rejection is maintained."

The rejection was maintained in the Office Action of 12/15/09 as follows:

"Applicants allegations on p. 5 of the Response of 11/10/09 have been considered and are not found persuasive. Applicants allege the present application is a 371 application of PCT/US2005/032821, which in turn claims priority to U.S. Application No. 09/996.069, which is the application number for the cited Bamdad '199 patent application publication. The first page of the PCT/US2005/032821 (WO2005/019269) publication is attached for the Examiner's review. Therefore, Bamdad '199 is not citable against the present application.

Response to Arguments

Applicants' comments are confusing.

First, no where on the attached first page of WO 2005/019269 does it mention "PCTNLS2005/032821". Applicants make the statement on the record that the instant application is a 371 for a PCT application that is wholly unrelated to the instant invention. "PCTNLS2005/032821" is an invention entitled "PROTEIN CONCENTRATE AND AN AQUEOUS STREAM CONTAINING WATER-SOLUBLE CARBOHYDRATES". The PCT No. for the instant 371 application is "PCTNLS2004/027954."

Second, inasmuch as the cover page for WO 2005/019299 ("PCT/US2004/027954") shows international "PCT/US2004/027954" claims priority to U.S. provisional 60/498,260 (filed 8/26/03) and is a CON or CIP of 09/99.6,099 (filed 11/27/02), Applicants have not carried the complete priority claim into the national stage-entry for the instant 371 application.

The published international application claims priority to the provisional application 60/498,260 and the priority claim is properly indicated in the 1st sentence of the 371 SPEC.

The only reference to 09/996,069 is in the supplemental box of the Request of PCT/US04/027954, which indicates that the international application is a continuation-in-part of 09/996,069. The international application cannot

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claim priority to any application filed more than a year before the international filing date. The '069 application was filed more than one year before the international filing date for PCT/US04/027954.

IF applicant wishes to claim priority to the "069 application, they need that reference in the international application, but they must also make a priority claim in the national stage application in either the first sentence of the specification, or on an application data sheet. There does not appear to be an ADS in the application, and there is no claim to priority to the "069 application" the first sentence of the 371 SPEC. Therefore, in this national stage application, there is no claim to priority to the "069 application. That means that the only priority date is to the provisional. Ifle in 2003, which would be the date for the ourcose of prior at.

This application is the national stage of PCT/US04/27954, and while the publication of this application indicates that the international application is related to 09996,069, it does not claim priority to it, and if Applicants want a priority claim in a national stage application, they must make the claim in that national stage application either in the 1st sentence of the SPEC or in an ADS.*

Applicants allegations on p. 6 of the Response of 6/15/10 have been considered and not found persuasive. Applicants allege the Petition to claim benefit to the same priority date for Bamdad '199 filed 6/15/10 removes Bamdad '199 as prior art.

Response to Arguments

Applicants petition to claim benefit of priority to the same filing date of Bamdad et al. (US 20030036199) has not been granted by the Petitions Branch. The instant claims are not entitled to the same filing date as the reference art, and therefore the rejection is maintained.

In addition, Bamdad '199 teaches and reads on Claim 196 for bivalent antibodies, Claims 197 and 198 drawn to the same subject matter of rejected Claims 13 and 14; and Claim 199 for kits.

The rejection is maintained.

Claim Rejections - 35 USC § 103

12. The rejection of Claims 1 and 17 (and new Claims 196 and 199) under 35 U.S.C. 103(a) as being unpatentable over Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01; cited in the PTO 892 form of 1/31/08) in view of Bamdad et al. (US

20030036199; published February 20, 2003; filed November 27, 2001; cited in the PTO 892 form of 8/22/07) is maintained.

Claims 196 and 199 are joined under this rejection as being drawn to a kit comprising the bivalent antibody.

The rejection was maintained in the Office Action of 10/31/08 as follows:

"Applicants' allegations on p. 9 of the Response of 7/31/08 have been considered but are not found persuasive. Applicants allege "Since Bamdad '199 is a priority application and therefore cannot be cited against the present application, this rejection is falls to be applicable to the present application."

Response to Arguments

See the examiner's comments under section 12 above as they apply here to the Bamdad reference. The rejection is maintained."

The rejection was maintained in the Office Action of 12/15/09 as follows:

"Applicants' allegations on pp. 7-8 of the Response of 11/10/09 have been considered but are not found persuasive. Applicants allege the amended Claim 1 includes the limitations for cancelled Claim 4.

Response to Arguments
The examiner submits Kufe discloses the single chain Fv or scFv antibody fragments at p. 14, lines 17-21. A single chain Fv is a "monovalent antibody" and is therefore taught by Kufe.

Bamdad teach bivalent and monovalent antibodies [0099; 0122; 0230] that bind to PSMGFR [0062] or fragments thereof [0277-278] of MUC1, and compositions comprising pharmaceutical compositions, and kits comprising the antibody [0011; 0143]. Finally, Bamdad teaches "When tumor cell lines, in which the MUC1 receptor is homogeneously expressed across the entire cell surface, are treated with an IgG antibody raised against the MGFR portion of the MUC1 receptor, the rate of cell proliferation is greatly enhanced, see FIG. 5. Since IgG antibodies are bivalent, i.e. one antibody simultaneously binds to two adjacent MGFR portions on the cell surface, these results demonstrate that the antibody acts as an activating ligand, mimicking the effect of a growth factor, which dimerizes MGFR portions, and thus triggers a cell proliferation signaling cascade which is consistent with signaling via the cytoplasmic tails of the receptors. This finding leads to two conclusions. First, an activating ligand(s) that binds to the MGFR portion of the MUC1 receptor causes inductive multimerization of the receptor. Secondly, an effective therapeutic strategy is therefore to block the MGFR portion of the receptor with a monomeric composition, thus preventing inductive multimerization and subsequent signaling cascades. For example, a single chain, or monovalent, antibody raised against the MGFR portion of the MUC1 receptor would function as an effective anti-cancer therapeutic" [0099]. Bamdad provides more than sufficient motivation to produce a monomeric form of an antibody to the PSMGFR domain in order to reduce cell proliferation of MUC1-expressing cells vis-a-vis decreased dimerization of the surface antigen."

Applicants allegations on pp. 6-7 of the Response of 6/15/10 have been considered and not found persuasive. Applicants allege the Petition to claim benefit to the same priority date for Bamdad '199 filed 6/15/10 removes Bamdad '199 as prior art.

Response to Arguments

Applicants petition to claim benefit of priority to the same filing date of Bamdad et al. (US 20030036199) has not been granted by the Petitions Branch. The instant claims are not entitled to the same filing date as the reference art, and therefore the rejection is maintained

In addition, Bamdad '199 teaches and reads on Claim 196 for bivalent antibodies, and Claim 199 for kits comprising the bivalent antibody.

The rejection is maintained.

New Grounds for Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue. 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating 4 obviousness or nonobviousness
- 13. Claims 17 and 199 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wreschner et al. (US 20050019324; published 1/27/05; filed 3/26/02; cited in the

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PTO 892 form of 1/31/08) in view of Kufe et al. (WO 02/22685; published 3/21/02; filed 12/11/01; cited in the PTO 892 form of 1/31/08).

Claims 17 and 199 are drawn to kits comprising the monovalent or bivalent antibody recognizing the sequence of SEQ ID NO: 36.

The claimed kits were prima facie obvious at the time of the invention.

Wreschner discloses an isolated antibody or fragment including monovalent and bivalent antibodies and fragments [0034; 0047], which specifically binds to an epitope in the extracellular region of an isoform of MUC1 protein [0019] where the epitope is located in the 15 amino acid sequence that resides at the N-terminal portion of the 59 amino acid segment which is located directly N-terminal to the transmembrane domain of the MUC1/Y, MUC1/X and MUC1/REP proteins [0044], a pharmaceutical composition comprising the antibody [0056]. The claims are considered to encompass an antibody binding to an unmodified sequence for the extracellular (SEQ ID NO:36 (native PSMGFR). Kufe appreciates compositions for administering as therapies or as diagnostics but does not disclose a kit comprising the anti-MGFR antibody as does Kufe.

Kufe discloses on p. 2, line 16 an extracellular domain of MUC-1 protein comprising amino acid residues corresponding to SEQ ID NO:36 for the PSMGFR domain, antibodies against the PSMGFR domain in both monovalent and bivalent forms (pp. 10-14; p. 31), and pharmaceutical compositions (p. 26-29). Because the claims recite any antibody binding to the PSMGFR domain, and Kufe teach such antibodies.

the claims are anticipated by the prior art. Kufe teaches preparing the antibodies in vials for administration which would be encompassed as elements within a kit.

It would have been prima facie obvious to have produced a kit comprising the antibody of the invention and one would have been reasonably assured of success in having done so at the time of the invention based on Wreschner and Kufe. Both Wreschner and Kufe disclose antibodies recognizing the sequence

TINVHDVETQFNQYKTEAASRYNLTISDVSVSDVPFPFSAQSGAG found in the extracellular domain of MUC1 protein. Both Wreschner and Kufe disclose compositions comprising the antibody for detecting the region of interest on the MUC1 protein, where such detection methods would have provided motivation to formulate the antibody into a kit. Specifically, Kufe teaches antibodies in vials, and therefore one of skill in the art would have been reasonably assured of success in having produced a kit for the antibody of the invention because kit/antibody combinations had been contemplated in the art at the time of the invention. For these reasons the kit comprising the anti-MGFR antibody or a binding fragment thereof would have been prima facie obvious.

Conclusion

- No claims are allowed.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883.
 The examiner can normally be reached on 8:00-4:00. Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/ Primary Examiner, Art Unit 1643